Billing Code 4410-09-P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

[Docket No. DEA-472]

Schedules of Controlled Substances: Temporary Placement of FUB-AMB into Schedule I

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Temporary amendment; temporary scheduling order.

SUMMARY: The Administrator of the Drug Enforcement Administration is issuing this temporary scheduling order to schedule the synthetic cannabinoid, methyl 2-(1-(4-fluorobenzyl)-1*H*-indazole-3-carboxamido)-3-methylbutanoate [FUB-AMB, MMB-FUBINACA, AMB-FUBINACA], and its optical, positional, and geometric isomers, salts, and salts of isomers into schedule I. This action is based on a finding by the Administrator that the placement of this synthetic cannabinoid into schedule I of the Controlled Substances Act is necessary to avoid an imminent hazard to the public safety. As a result of this order, the regulatory controls and administrative, civil, and criminal sanctions applicable to schedule I controlled substances will be imposed on persons who handle (manufacture, distribute, reverse distribute, import, export, engage in research, conduct instructional activities or chemical analysis, or possess), or propose to handle, FUB-AMB.

DATES: This temporary scheduling order is effective [INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER], until November 4, 2019. If this order is extended or made permanent, the DEA will publish a document in the *Federal Register*.

FOR FURTHER INFORMATION CONTACT: Michael J. Lewis, Diversion Control Division, Drug Enforcement Administration; Mailing Address: 8701 Morrissette Drive, Springfield, Virginia 22152; Telephone: (202) 598-6812.

SUPPLEMENTARY INFORMATION:

Legal Authority

Section 201 of the Controlled Substances Act (CSA), 21 U.S.C. 811, provides the Attorney General with the authority to temporarily place a substance into schedule I of the CSA for two years without regard to the requirements of 21 U.S.C. 811(b) if he finds that such action is necessary to avoid an imminent hazard to the public safety. 21 U.S.C. 811(h)(1). In addition, if proceedings to control a substance are initiated under 21 U.S.C. 811(a)(1), the Attorney General may extend the temporary scheduling[1] for up to one year. 21 U.S.C. 811(h)(2).

Where the necessary findings are made, a substance may be temporarily scheduled if it is not listed in any other schedule under section 202 of the CSA, 21 U.S.C. 812, or if there is no exemption or approval in effect for the substance under section 505 of the Federal Food, Drug, and Cosmetic Act (FDCA), 21 U.S.C. 355. 21 U.S.C. 811(h)(1).

[1] Though DEA has used the term "final order" with respect to temporary scheduling orders in the past, this notification adheres to the statutory language of 21 U.S.C. 811(h), which refers to a "temporary scheduling order." No substantive change is intended.

The Attorney General has delegated scheduling authority under 21 U.S.C. 811 to the Administrator of the DEA. 28 CFR 0.100.

Background

Section 201(h)(4) of the CSA 21 U.S.C. 811(h)(4), requires the Administrator to notify the Secretary of the Department of Health and Human Services (HHS) of his intention to temporarily place a substance into schedule I of the CSA.[2] The Acting Administrator transmitted notice of his intent to place FUB-AMB into schedule I on a temporary basis to the Assistant Secretary for Health by letter dated May 19, 2017. The Assistant Secretary responded to this notice by letter dated June 9, 2017, and advised that based on a review by the Food and Drug Administration (FDA), there were no active investigational new drug applications or approved new drug applications for FUB-AMB. The Assistant Secretary also stated that the HHS has no objection to the temporary placement of FUB-AMB into schedule I of the CSA. The DEA has taken into consideration the Assistant Secretary's comments as required by 21 U.S.C. 811(h)(4). FUB-AMB is not currently listed in any schedule under the CSA, and no exemptions or approvals are in effect for FUB-AMB under section 505 of the FDCA, 21 U.S.C. 355. The DEA has found that the control of FUB-AMB in schedule I on a temporary basis is necessary to avoid an imminent hazard to the public safety, and as required by 21 U.S.C. 811(h)(1)(A), a notice of intent to temporarily schedule FUB-AMB was published in the *Federal Register* on September 11, 2017. 82 FR 42624.

[2] As discussed in a memorandum of understanding entered into by the Food and Drug Administration (FDA) and the National Institute on Drug Abuse (NIDA), the FDA acts as the lead agency within the Department of Health and Human Service (HHS) in carrying out the Secretary's scheduling responsibilities under the CSA, with the concurrence of NIDA. 50 FR 9518, Mar. 8, 1985. The Secretary of the HHS has delegated to the Assistant Secretary for Health of the HHS the authority to make domestic drug scheduling recommendations. 58 FR 35460, July 1, 1993.

To find that placing a substance temporarily into Schedule I of the CSA is necessary to avoid an imminent hazard to the public safety, the Administrator is required to consider three of the eight factors set forth in section 201(c) of the CSA, 21 U.S.C. 811(c): The substance's history and current pattern of abuse; the scope, duration and significance of abuse; and what, if any, risk there is to the public health. 21 U.S.C. 811(h)(3). Consideration of these factors includes actual abuse, diversion from legitimate channels, and clandestine importation, manufacture, or distribution. 21 U.S.C. 811(h)(3).

A substance meeting the statutory requirements for temporary scheduling may only be placed in schedule I. 21 U.S.C. 811(h)(1). Substances in schedule I are those that have a high potential for abuse, no currently accepted medical use in treatment in the United States, and a lack of accepted safety for use under medical supervision. 21 U.S.C. 812(b)(1).

Available data and information for FUB-AMB, summarized below, indicate that this synthetic cannabinoid (SC) has a high potential for abuse, no currently accepted medical use in treatment in the United States, and a lack of accepted safety for use under medical supervision. The DEA's three-factor analysis and the Assistant Secretary's June 9, 2017 letter are available in their entirety under the tab "Supporting Documents" of the public docket of this action at www.regulations.gov under FDMS Docket ID: DEA-2017-0010 (Docket Number DEA-472).

FUB-AMB

The illicit use of the synthetic cannabinoid (SC) methyl 2-(1-(4-fluorobenzyl)-1*H*-indazole-3-carboxamido)-3-methylbutanoate (Street names: FUB-AMB, MMB-

FUBINACA, AMB-FUBINACA) has dramatically increased over the past 12 months posing an imminent threat to public safety.

Synthetic Cannabinoids

SCs are substances synthesized in laboratories that mimic the biological effects of delta-9-tetrahydrocannabinol (THC), the main psychoactive ingredient in marijuana. It is believed that SCs were first introduced on the designer drug market in several European countries as "herbal incense" before the initial encounter in the United States by U.S. Customs and Border Protection (CBP) in November 2008. From 2009 to the present, misuse and abuse of SCs has increased in the United States with law enforcement encounters describing SCs applied onto plant material and in designer drug products intended for human consumption. It has been demonstrated that the substances and the associated designer drug products are abused for their psychoactive properties. With many generations of SCs having been encountered since 2009, FUB-AMB is one of the latest, and the abuse of these substances is negatively impacting communities.

As observed by the DEA and CBP, SCs originate from foreign sources, such as China. Bulk powder substances are smuggled via common carrier into the United States and find their way to clandestine designer drug product manufacturing operations located in residential neighborhoods, garages, warehouses, and other similar destinations throughout the country. According to online discussion boards and law enforcement encounters, applying by spraying or mixing the SCs with plant material provides a vehicle for the most common route of administration—smoking (using a pipe, a water pipe, or rolling the drug-laced plant material in cigarette papers).

FUB-AMB has no accepted medical use in the United States. Use of this specific SC has been reported (see factor 6) to result in adverse effects in humans. Use of other SCs has resulted in signs of addiction and withdrawal and based on the similar pharmacological profile of FUB-AMB, it is believed that there will be similar observed adverse effects.

FUB-AMB is a SC that has pharmacological effects similar to the Schedule I hallucinogen THC and other temporarily and permanently controlled Schedule I synthetic cannabinoid substances. In addition, the misuse of FUB-AMB has been associated with multiple overdoses requiring emergency medical intervention (see factor 6). With no approved medical use and limited safety or toxicological information, FUB-AMB has emerged on the designer drug market, and the abuse of this substance for its psychoactive properties is concerning.

Factor 4. History and Current Pattern of Abuse

Synthetic cannabinoids have been developed by researchers over the last 30 years as tools for investigating the endocannabinoid system, (e.g. determining CB1 and CB2 receptor activity). The first encounter of SCs within the United States occurred in November 2008 by CBP. Since then the popularity of SCs and their associated products has increased steadily as evidenced by law enforcement seizures, public health information, and media reports. FUB-AMB was originally encountered in 2014, but has since seen a large increase in its illicit use. The misuse of FUB-AMB has been associated with multiple overdoses involving emergency medical intervention.

Research and clinical reports have demonstrated that SCs are applied onto plant material so that the material may be smoked as users attempt to obtain a euphoric and/or

psychoactive "high," believed to be similar to marijuana. Data gathered from a published study, and supplemented by discussions on Internet Web sites, demonstrate that these products are being abused mainly by smoking for their psychoactive properties. The adulterated products are marketed as "legal" alternatives to marijuana. In recent overdoses, FUB-AMB has been encountered in the form of herbal products, similar to the SCs that have been previously available.

The powder form of SCs is typically dissolved in solvents (e.g., acetone) before being applied to plant material or dissolved in a propellant intended for use in electronic cigarette devices. Law enforcement personnel have encountered various application methods including buckets or cement mixers in which plant material and one or more SCs are mixed together, as well as large areas where the plant material is spread out so that a dissolved SC mixture can be applied directly. Once mixed, the SC plant material is then allowed to dry before manufacturers package the product for distribution, ignoring any control mechanisms to prevent contamination or to ensure a consistent, uniform concentration of the substance in each package. Adverse health consequences may also occur from directly ingesting the drug during the manufacturing process. FUB-AMB, similar to other SCs, has been encountered in the form of dried leave or herbal blends.

The designer drug products laced with SCs, including FUB-AMB, are often sold under the guise of "herbal incense" or "potpourri," use various product names, and are routinely labeled "not for human consumption." Additionally, these products are marketed as a "legal high" or "legal alternative to marijuana" and are readily available over the Internet, in head shops, or sold in convenience stores. There is an incorrect assumption that these products are safe, that they are a synthetic form of marijuana, and

that labeling these products as "not for human consumption" is a legal defense to criminal prosecution.

It is believed most abusers of SCs or SC-related products are smoking the product following application to plant material. Law enforcement has also begun to encounter new variations of SCs in liquid form. It is believed abusers have been applying the liquid to hookahs or "e-cigarettes," which allows the user to administer a vaporized liquid that can be inhaled.

Factor 5. Scope, Duration and Significance of Abuse

SCs including FUB-AMB continue to be encountered on the illicit market regardless of scheduling actions that attempt to safeguard the public from the adverse effects and safety issues associated with these substances. Novel substances are encountered each month, differing only by small modifications intended to avoid prosecution while maintaining the pharmacological effects. Law enforcement and health care professionals continue to report the abuse of these substances and their associated products.

As described by the National Institute on Drug Abuse (NIDA), many substances being encountered in the illicit market, specifically SCs, have been available for years but have reentered the marketplace due to a renewed popularity. The threat of serious injury to the individual following the ingestion of FUB-AMB and other SCs persists.

The following information details information obtained through NFLIS[3] (queried on May 16, 2017), including dates of first encounter, exhibits/reports, and locations.

[3] The National Forensic Laboratory Information System (NFLIS) is a national drug forensic laboratory reporting system that systematically collects results from drug chemistry analyses conducted by state and local forensic laboratories in the United States.

FUB-AMB: NFLIS–6,522 reports, first encountered in June 2014, locations include: Arizona, Arkansas, , California, Colorado, Florida, Georgia, Idaho, Illinois, Indiana, Iowa, Kansas, Kentucky, Louisiana, Maryland, Massachusetts, Minnesota, Mississippi, Missouri, New Hampshire, New Jersey, New Mexico, New York, North Dakota, Ohio, Oklahoma, Pennsylvania, Rhode Island, South Carolina, Tennessee, Texas, Utah, Virginia, Wisconsin and Wyoming.

Factor 6. What, if Any, Risk There Is to the Public Health

FUB-AMB has been identified in overdose cases attributed to its abuse. Adverse health effects reported from these incidents involving FUB-AMB have included: Nausea, persistent vomiting, agitation, altered mental status, seizures, convulsions, loss of consciousness, and cardiotoxicity. By sharing pharmacological similarities with Schedule I substances (Δ9-THC, JWH-018 and other temporarily and permanently controlled schedule I SCs), SCs pose a risk to the abuser. While these adverse effects have been shown by a variety of SCs, similar concerns remain regarding the welfare of the user as it relates to abuse of products laced with FUB-AMB. The risk of adverse health effects is further increased by the fact that similar products vary in the composition and concentration of SCs applied on the plant material.

Finding of Necessity of Schedule I Placement to Avoid Imminent Hazard to Public Safety

In accordance with 21 U.S.C. 811(h)(3), based on the available data and information summarized above, the continued uncontrolled manufacture, distribution, importation, exportation, conduct of research and chemical analysis, possession, and abuse of FUB-AMB poses an imminent hazard to the public safety. The DEA is not aware of any

currently accepted medical uses for FUB-AMB in the United States. A substance meeting the statutory requirements for temporary scheduling, 21 U.S.C. 811(h)(1), may only be placed in schedule I. Substances in Schedule I are those that have a high potential for abuse, no currently accepted medical use in treatment in the United States, and a lack of accepted safety for use under medical supervision. Available data and information for FUB-AMB indicate that this SC has a high potential for abuse, no currently accepted medical use in treatment in the United States, and a lack of accepted safety for use under medical supervision. As required by section 201(h)(4) of the CSA, 21 U.S.C. 811(h)(4), the Administrator, through a letter dated May 19, 2017, notified the Assistant Secretary of the DEA's intention to temporarily place FUB-AMB in Schedule I.

A notice of intent was subsequently published in the *Federal Register* on September 11, 2017. 82 FR 42624.

Conclusion

In accordance with the provisions of section 201(h) of the CSA, 21 U.S.C. 811(h), the Administrator considered available data and information, and herein set forth the grounds for his determination that it is necessary to temporarily schedule methyl 2-(1-(4-fluorobenzyl)-1*H*-indazole-3-carboxamido)-3-methylbutanoate [FUB-AMB, MMB-FUBINACA, AMB-FUBINACA]into schedule I of the CSA to avoid an imminent hazard to the public safety.

Because the Administrator hereby finds it necessary to temporarily place this SC into schedule I of the CSA to avoid an imminent hazard to the public safety, this temporary order scheduling this substance is effective on the date of publication in the *Federal Register*, and is in effect for a period of two years, with a possible extension of one

additional year, pending completion of the regular (permanent) scheduling process. 21 U.S.C. 811(h) (1) and (2).

The CSA sets forth specific criteria for scheduling a drug or other substance. Permanent scheduling actions in accordance with 21 U.S.C. 811(a) are subject to formal rulemaking procedures done "on the record after opportunity for a hearing" conducted pursuant to the provisions of 5 U.S.C. 556 and 557. 21 U.S.C. 811. The permanent scheduling process of formal rulemaking affords interested parties with appropriate process and the government with any additional relevant information needed to make a determination. Final decisions that conclude the permanent scheduling process of formal rulemaking are subject to judicial review. 21 U.S.C. 877. Temporary scheduling orders are not subject to judicial review. 21 U.S.C. 811(h)(6).

Requirements for Handling

Upon the effective date of this final order, FUB-AMB will be subject to the regulatory controls and administrative, civil, and criminal sanctions applicable to the manufacture, distribution, reverse distribution, importation, exportation, engagement in research, and conduct of instructional activities or chemical analysis with, and possession of schedule I controlled substances including the following:

1. *Registration.* Any person who handles (manufactures, distributes, reverse distributes, imports, exports, engages in research, or conducts instructional activities or chemical analysis with, or possesses), or who desires to handle, FUB-AMB must be registered with the DEA to conduct such activities pursuant to 21 U.S.C. 822, 823, 957, and 958 and in accordance with 21 CFR parts 1301 and 1312, as of [INSERT DATE OF PUBLICATION IN FEDERAL REGISTER]. Any person who currently handles FUB-

AMB and is not registered with the DEA, must submit an application for registration and may not continue to handle FUB-AMB as of [INSERT DATE OF PUBLICATION IN FEDERAL REGISTER], unless the DEA has approved that application for registration. Retail sales of schedule I controlled substances to the general public are not allowed under the CSA. Possession of any quantity of this substance in a manner not authorized by the CSA on or after [INSERT DATE OF PUBLICATION IN FEDERAL REGISTER] is unlawful and those in possession of any quantity of this substance may be subject to prosecution pursuant to the CSA.

2. *Disposal of stocks.* Any person who does not desire or is not able to obtain a schedule I registration to handle FUB-AMB must surrender all quantities of currently held FUB-AMB.

3. *Security*. FUB-AMB is subject to schedule I security requirements and must be handled and stored pursuant to 21 U.S.C. 821, 823, 871(b), and in accordance with 21 CFR 1301.71–1301.93, as of [INSERT DATE OF PUBLICATION IN FEDERAL REGISTER].

4. *Labeling and Packaging*. All labels, labeling, and packaging for commercial containers of FUB-AMB must be in compliance with 21 U.S.C. 825, 958(e), and be in accordance with 21 CFR part 1302. Current DEA registrants shall have 30 calendar days from [INSERT DATE OF PUBLICATION IN FEDERAL REGISTER], to comply with all labeling and packaging requirements.

5. *Inventory*. Every DEA registrant who possesses any quantity of FUB-AMB on the effective date of this order, must take an inventory of all stocks of this substance on hand, pursuant to 21 U.S.C. 827 and 958, and in accordance with 21 CFR 1304.03, 1304.04,

and 1304.11. Current DEA registrants shall have 30 calendar days from the effective date of this order to be in compliance with all inventory requirements. After the initial inventory, every DEA registrant must take an inventory of all controlled substances (including FUB-AMB) on hand on a biennial basis, pursuant to 21 U.S.C. 827 and 958, and in accordance with 21 CFR 1304.03, 1304.04, and 1304.11.

6. *Records*. All DEA registrants must maintain records with respect to FUB-AMB pursuant to 21 U.S.C. 827 and 958(e), and in accordance with 21 CFR parts 1304 and 1312, 1317 and § 1307.11. Current DEA registrants authorized to handle FUB-AMB shall have 30 calendar days from the effective date of this order to be in compliance with all recordkeeping requirements.

7. *Reports*. All DEA registrants who manufacture or distribute FUB-AMB must submit reports pursuant to 21 U.S.C. 827 and in accordance with 21 CFR parts 1304 and 1312 as of [INSERT DATE OF PUBLICATION IN FEDERAL REGISTER].

8. *Order Forms*. All DEA registrants who distribute FUB-AMB must comply with order form requirements pursuant to 21 U.S.C. 828 and in accordance with 21 CFR part 1305 as of [INSERT DATE OF PUBLICATION IN FEDERAL REGISTER].

9. *Importation and Exportation*. All importation and exportation of FUB-AMB must be in compliance with 21 U.S.C. 952, 953, 957, 958, and in accordance with 21 CFR part 1312 as of [INSERT DATE OF PUBLICATION IN FEDERAL REGISTER].

10. *Quota*. Only DEA registered manufacturers may manufacture FUB-AMB in accordance with a quota assigned pursuant to 21 U.S.C. 826 and in accordance with 21 CFR part 1303 as of [INSERT DATE OF PUBLICATION IN FEDERAL REGISTER].

11. *Liability*. Any activity involving FUB-AMB not authorized by, or in violation of the CSA, occurring as of [INSERT DATE OF PUBLICATION IN FEDERAL REGISTER], is unlawful, and may subject the person to administrative, civil, and/or criminal sanctions.

Regulatory Matters

Section 201(h) of the CSA, 21 U.S.C. 811(h), provides for a temporary scheduling action where such action is necessary to avoid an imminent hazard to the public safety. As provided in this subsection, the Attorney General may, by order, schedule a substance in schedule I on a temporary basis. Such an order may not be issued before the expiration of 30 days from (1) the publication of a notice in the *Federal Register* of the intention to issue such order and the grounds upon which such order is to be issued, and (2) the date that notice of the proposed temporary scheduling order is transmitted to the Assistant Secretary. 21 U.S.C. 811(h)(1).

Inasmuch as section 201(h) of the CSA directs that temporary scheduling actions be issued by order and sets forth the procedures by which such orders are to be issued, the DEA believes that the notice and comment requirements of the Administrative Procedure Act (APA) at 5 U.S.C. 553, do not apply to this temporary scheduling action. In the alternative, even assuming that this action might be subject to 5 U.S.C. 553, the Administrator finds that there is good cause to forgo the notice and comment requirements of section 553, as any further delays in the process for issuance of temporary scheduling orders would be impracticable and contrary to the public interest in view of the manifest urgency to avoid an imminent hazard to the public safety.

Further, the DEA believes that this temporary scheduling action is not a "rule" as defined by 5 U.S.C. 601(2), and, accordingly, is not subject to the requirements of the Regulatory Flexibility Act (RFA). The requirements for the preparation of an initial regulatory flexibility analysis in 5 U.S.C. 603(a) are not applicable where, as here, the DEA is not required by the APA or any other law to publish a general notice of proposed rulemaking.

Additionally, this action is not a significant regulatory action as defined by Executive Order 12866 (Regulatory Planning and Review), section 3(f), and, accordingly, this action has not been reviewed by the Office of Management and Budget.

This action will not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. Therefore, in accordance with Executive Order 13132 (Federalism) it is determined that this action does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

As noted above, this action is an order, not a rule. Accordingly, the Congressional Review Act (CRA) is inapplicable, as it applies only to rules. However, if this were a rule, pursuant to the CRA, "any rule for which an agency for good cause finds that notice and public procedure thereon are impracticable, unnecessary, or contrary to the public interest, shall take effect at such time as the federal agency promulgating the rule determines." 5 U.S.C. 808(2). It is in the public interest to schedule this substance immediately to avoid an imminent hazard to the public safety. This temporary scheduling action is taken pursuant to 21 U.S.C. 811(h), which is specifically designed to enable the DEA to act in an expeditious manner to avoid an imminent hazard to the

public safety. 21 U.S.C. 811(h) exempts the temporary scheduling order from standard notice and comment rulemaking procedures to ensure that the process moves swiftly. For the same reasons that underlie 21 U.S.C. 811(h), that is, the need to move quickly to place this substance into schedule I because it poses an imminent hazard to public safety, it would be contrary to the public interest to delay implementation of the temporary scheduling order. Therefore, this order shall take effect immediately upon its publication. The DEA has submitted a copy of this temporary order to both Houses of Congress and to the Comptroller General, although such filing is not required under the Small Business Regulatory Enforcement Fairness Act of 1996 (Congressional Review Act), 5 U.S.C. 801-808, because as noted above, this action is an order, not a rule.

List of Subjects in 21 CFR Part 1308

Administrative practice and procedure, Drug traffic control, Reporting and recordkeeping requirements.

For the reasons set out above, the DEA amends 21 CFR part 1308 as follows:

PART 1308—SCHEDULES OF CONTROLLED SUBSTANCES

1. The authority citation for part 1308 continues to read as follows:

Authority: 21 U.S.C. 811, 812, 871(b), 956(b), unless otherwise noted.

2. Amend § 1308.11 by adding paragraph (h)(18) to read as follows:

§ 1308.11 Schedule I.

* * * * *

(h) * * *

(18) methyl 2-(1-(4-fluorobenzyl)-1*H*-indazole-3-carboxamido)-3-methylbutanoate, its optical, positional, and geometric isomers, salts and salts of isomers (Other names: FUB-AMB, MMB-FUBINACA, AMB-FUBINACA)……(7021)

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Dated: October 27, 2017.

Robert W. Patterson,
Acting Administrator.

[FR Doc. 2017-24010 Filed: 11/2/2017 8:45 am; Publication Date: 11/3/2017]